

REMARKS

An interview was conducted with the Examiner on July 14, 2008. Six amended claims were presented to the Examiner. However none of the offered claims were discussed in depth. The Examiner stated she believed the amended claims were getting closer to describing the invention and that progress was being made to achieve allowable claims. She also recommended that the Applicant further define the fused junctures. The amended claims are offered in compliance with the Examiner's comments.

The Examiner has rejected claims under 103(a) citing Rogers 5,607,468 in view of Holman et al 6,319,276 and further in view of Guiset 4,183,102. It is well recognized that Rogers teaches longitudinal oriented sealing bands of the inner and outer sleeve in contrast to the circumferential fused junctures of the Applicant's invention. The fused juncture of the inner and outer wall of the Applicants invention form multiple circumferential flexible, un-pressurized bands which allow the graft to bend to conform to the blood vessel. This is not possible with Rogers. Rogers also is made from compliant material with the result that pressure is transferred to the thin vessel walls of the cerebral circulatory system. In addition, Rogers does not contain an internal radial reinforcement structure to maintain the shape of the graft within the vessel walls. The structure taught by Rogers may be acceptable for the thick straight walls of aortas but this structure not suitable for the tortuous and thin walled vessel of the cerebral circulatory system.

Figures 2 and 4 of Rogers demonstrate an uneven interior lumen surface. The surface is not smooth. This uneven surface can facilitate the growth of blood clots, thereby jeopardizing the purpose of the inserting the graft. The Applicant respectfully traverses the rejection incorporating Rogers.

Holman does not remedy these deficiencies. Review of the drawings indicates it teaches sparse and frequently separated use of "tubulars". See Figures 4 and 6. Holman relies on metal spring tensioned strips to provide structural support for the graft. See Col. 1, lines 58 through 64. The Holman patent pertains to "a device and method

for repairing an aneurysm or the like in a vessel, such as the aorta." Col. 2, line 61 through 64.

Holman also teaches use of expanding hardening agents inserted into the tubules. Holman states "this embodiment is of particular use for fusing such grafts in large vessels such as the aorta or pulmonary arteries". Col. 3 line 50 to 52. The materials comprising the Holman graft are not limited to non compliant materials. Therefore it is possible that dangerous pressure could be exerted on the fragile cerebral vessel walls. Further, the inflatable tubulars "comprise only a small fraction of the sleeve". See Col. 4, line 11 and 12. There is no structure comparable to the fused junctures or sealed inflation chambers containing inelastic web reinforcement taught by the Applicant's invention. Again, the Applicant's structure allows bending of the graft to conform to the vessel, facilitates anchoring of the graft within the vessel and exerts no pressure upon the vessel walls.

The sparse placement of the inflatable tubulars signifies that inflation pressure is not the principal means for the device retaining its shape. This function is performed by wire inserts that "provide a constant spring tension". Col. 1, line 62 Also, please compare Applicant's Figure 1D to Holman Figure 4.

There is no motivation within Holman to adapt it to the tortuous and stenotic cerebral circulatory system. Further, there must be an identification of a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements (elements of Rogers, Holman Guiset and Lazim) in the manner of the Applicant's invention. This is the duty of the Examiner. Further, the Examiner must expressly articulate the underlying analysis supporting a proffered "apparent reason". Mere conclusory statements are insufficient to sustain a rejection under 103(a). See KSR International Co. vs. Teleflex Inc. et al., 550 U.S. ____ (2007).

Holman does not teach a circumferential fused juncture that provides bending sites for the graft. It demonstrates a helically wound inflatable tube reinforcing the end of a sleeve and used to anchor the sleeve proximate to an enlarged section of vessel wall, i.e., aneurysm. See Figure 6. Therefore combining Rogers with Holman does not create the fused junctures of the Applicant's invention. There is no suggestion for the

variable width of a fused juncture around the graft circumference. This can function like a hinge and allow bending of the graft between the rigid and inflexible inflation chambers. Recall there is no inflation pressure on the fused juncture. Applicant respectfully traverses the rejection incorporating Holman.

Guiset, 4,183,102, has been cited by the Examiner as teaching use of non-elastic web reinforcements resulting in a reinforced inflation chamber. The Applicant disagrees. Guiset teaches radially oriented *partition walls* that connect the inner and outer walls of the graft. See Guiset Figures 8 and 9 (item 49). Please compare these figures to Applicant's Figure 1E and 1F (item 20). Further, the outer wall of Guiset is expandable, transferring pressure to the fragile cerebral vessel. The longitudinal membrane, which the Examiner equates to the Applicant's web reinforcements, are impermeable. The Applicant's web reinforcements are individual or separate narrow struts or web components. They do not impede the flow of fluid. The Guiset longitudinal membrane does impede the flow of fluid. See Col. 6, lines 39 through 47 and lines 58 through 65. The Applicant respectfully traverses the rejection incorporating Guiset.

The Examiner has further cited Lazim, 5,330,528. It must be emphasized the Lazim does not teach circumferential fused junctures allowing un-pressurized bending of the graft. Compare Figure 1D of Applicant's invention to Figure 1 of Lazim. Lazim does not teach the web reinforcement structure of the Applicant's invention. See Applicant's drawing 1F in comparison to Lazim Figure 5. Applicant respectfully traverses the rejection incorporating Lazim.

The Examiner has cited Samson 5,370,681 in rejection of claims 20 and 21 for a curable fluid. However claims 20 and 21 are dependent upon claim 1 which is an allowable claim for the reason set forth herein.

None of the prior art cited by the Examiner teaches key components of the Applicant's invention. These deficiencies include but are not limited to fused junctures having fixed diameters. The fused junctures are not subject to inflation pressure. The fused juncture can be manufactured to have non uniform spacing around the circumference and thereby allowing the inflated graft to assume a non-linear shape.

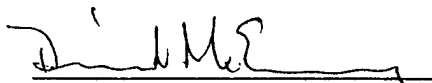
The inflation chambers command the greatest surface area of the Applicant's graft. They are bounded by non compliant inner and outer wall. The dimensions of the inflation chamber are further controlled by the inelastic web reinforcement attached to the inner and outer wall of the two wall graft. The web reinforcement is just that, a web of individual, separate straps or struts tying the two walls together. Due to its architecture, fluid is quickly disbursed through each inflation chamber.

None of the prior art cited by the Examiner is applicable to treatment of atherosclerotic plaque as identified in the Applicant patent application. The Applicant's invention comprises a one step endovascular treatment device that combines functions of a balloon, a stent and protective devices in a single device and which can be deployed within a short time period. The device eliminates the long term risk of regrowth of the plaque through the device. To accomplish this, distinct characteristics including (i) the device has to be able to adapt and conform to the tortuous nature of the blood vessels in its fully deployed and pressurized form with the least amount of stress on the wall to avoid perforation and bleeding; (ii) the graft has to have enough radial force to open the thickened and narrowed blood vessels with strict adherence to predetermine size and shape to avoid outward bulging of the outer wall of the graft which will result in rupture of the blood vessel, or inward bulging of the inner wall of the graft which will result in narrowing of the graft lumen which will defeat the purpose of the device; (iii) the device has to be able to anchor to the wall of the blood vessel with minimal stress; (iv) the device has to allow blood flow to side branches arising from the main treated blood vessels; and (v) the device has to have a large and smooth inner lumen in its fully deployed form to allow blood to flow in sufficient amount to the brain without the risk of clot forming on the inner wall which will occur if the inner wall is not smooth.

SUMMARY

No new matter has been added. A Request for Continued Examination is transmitted with this response. Also transmitted is an Information Disclosure Statement. It is believed the claims are now in order for allowance and such action is respectfully requested.

Respectfully Submitted,

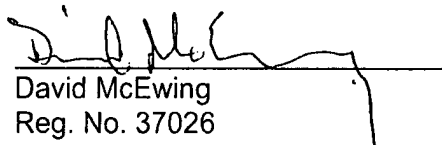


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